The CardioSEAL Septal Occlusion System
Instructions for Use
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The CardioSEAL Septal Occlusion System

Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practicioner).

1. HUMANITARIAN USE DEVICE: Authorized by Federal law for use in patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and require closure of the fenestration. The effectiveness of this device for this use has not been demonstrated.

2. PRODUCT DESCRIPTION:
The CardioSEAL Septal Occlusion System consists of two primary components:

- The CardioSEAL (Occluder), which is constructed of a metal (MP35n) framework to which polyester fabric is attached, and
- The Delivery Catheter, a coaxial polyurethane catheter designed specifically to facilitate attachment, loading, delivery and deployment of the CardioSEAL to the defect.

3. INDICATION FOR USE:
The CardioSEAL Septal Occlusion System is authorized by Federal (USA) law as a Humanitarian Use Device for use in the following indication only:

> Patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and require closure of the fenestration.

The effectiveness of this device in this indication has not been demonstrated.

4. CONTRAINDICATIONS:
Presence of thrombus at the intended site of implant. or documented evidence of venous thrombus in the vessels through which access to the defect is gained.

Active endocarditis, or other infections producing a bacteremia.

Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate size sheath.

Patients whose defect is too small to allow the 11 F sheath to cross the defect.

Anatomy in which the CardioSEAL size required would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins.

Patients with coagulation disorders who are unable to take Aspirin, Coumadin, or other anticoagulants.

5. WARNINGS:

This device should only be used by those physicians trained in transcatheter defect closure techniques, and by those physicians prepared to provide long term follow up patient monitoring.

Physicians attempting to recover an embolized device should be limited to those that have completed appropriate device retrieval technique training.

Embolized CardioSEAL devices should be removed. Dislodged CardioSEALs have embolized to the pulmonary and systemic vasculature.

Embolized CardioSEALs may disrupt critical cardiac functions. Physicians must be prepared to deal with urgent requirements to extract or move embolized CardioSEALs that result in critical hemodynamic compromise.

Embolized CardioSEALs should not be withdrawn through intracardiac structures unless they have been adequately collapsed within a sheath. Devices that are not adequately collapsed within a sheath may entangle with valvular or other cardiac structures.

Do not attempt to repair or reuse damaged product. Do not reuse or resterilize product. Return to manufacturer.

6. PRECAUTIONS:

6.1 CardioSEAL – Handling Precautions

Do not use the system if, during loading of the CardioSEAL, difficulty is encountered in transferring the CardioSEAL into the loader or from loader to the pod of the delivery catheter.

Do not modify the delivery catheter or CardioSEAL. Modification may result in damage that can result in complications such as embolism, framework fracture, failure to release, and improper seating at the target defect.

6.2 CardioSEAL – Sizing Precautions

The use of a compliant balloon catheter to determine defect localization is recommended.

Accurate defect sizing is criticial to CardioSEAL selection. Defect sizing methods, such as contrast angiography, echocardiography and – or balloon sizing should be considered as procedural alternatives. The defect and surrounding structures should be fully examined in multiple planes to assure proper sizing of the CardioSEAL.

The anatomic area surrounding the target defect should have enough contiguous structure to support the CardioSEAL.

6.3 CardioSEAL – Procedural Precautions

The ability of the patient to remain still during implantation must be weighed against the need for "conscious" sedation versus general anesthesia. The decision to use general anesthesia in any individual patient is subject to physician judgement.

Patients should be fully heparinized throughout the procedure using adequate dosing so as to keep the ACT greater than 200 msec.

Antibiotic therapy periprocedurally is recommended to reduce the risk of perioperative infection.

The use of Transesophogeal Echocardiography (TEE) should be considered as a potential aid in placing the CardioSEAL. If used, the patient's esophogeal anatomy must be adequate for placement and manipulation of the TEE probe.

Placement of the CardioSEAL requires the use of fluoroscopic X-ray guidance. The risk of increased x-ray exposure for patients who are pregnant must be weighed against the potential benefits of the technique.

The patient's vasculature should be sufficient to accommodate the 11 F sheath required to deliver the CardioSEAL.

The Right Femoral Vein is recommended for vascular access although physicians should consider defect location and the route of introducer sheath travel relative to the potential for access in selecting the venous access site.

An 11F, 75cm long, hemostasis control introducer sheath with NIH type curve is recommended for CardioSEAL delivery. Sheath curve shape may need modification based on individual patient conditions and defect location. As the use of long sheaths represents a potential risk of air embolus, care should be taken to insure adequate irrigation and 'backfilling' of the sheath with saline during removal of the dilator in order to avoid air entry.

Introducer sheaths longer than 80 cm will prohibit the complete extrusion of the CardioSEAL from the sheath during delivery to the defect.

A 14F or 16F short introducer sheath may be placed coaxially over the long introducer sheath prior to long sheath insertion if the physician believes the circumstances of the case raise the potential for device retrieval after attempted placement.

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A delivery catheter of equivalent or larger pod size must be used with the CardioSEAL to avoid damage to the implant during loading and deployment.

Malpositioned CardioSEALs may interfere with cardiac, vascular or valvular structures, depending on patient anatomy. Physicians should consider removing malpositioned CardioSEALs in these patients.

6.4 CardioSEAL – Post Implant Precautions

The time course of endothelialization of the device is unknown. Patients should receive appropriate endocarditis prophylaxis for the six months following implantation. The decision to continue prophylactic treatment after six months is subject to physician judgement.

Patients should be treated with antiplatelet/anticoagulation therapy, such as Aspirin (see Section 8 Clinical Studies for the dosage used in the High-risk study) for six-months following implant. The decision to use medical treatment other than Aspirin is subject to physician judgement of the patient's overall risk of embolic potential given their specific medical condition. The decision to continue medical treatment beyond six months is subject to physician judgement.

All CardioSEALs are non-ferromagnetic. Independent studies of CardioSEAL in a 1.5 Tesla magnetic field demonstrate no movement of the CardioSEAL. However, MRI image quality may be compromised in the area of the implant.

7. ADVERSE EVENTS:

7.1 Observed Adverse Events:

A total of 83 patients with a fenestrated Fontan were enrolled in a 292 patient multi-center High-risk study. A total of 93 adverse events were recorded among the 83 patients enrolled in the study for closure of their fenestrated Fontan. These adverse events were classified as Serious (2), Moderately Serious (26), Not Serious (65) and were linked to either the device, the implant procedure, the catheterization procedure, or other causes, such as a pre-existing condition. Adverse events (13) that were classified as Serious or Moderately Serious and definitely or probably related to the device, the implant procedure or the catheterization are shown in Table 1.

Fenestrated Fontan Patients (N= 83) Table 1

	Moderately Serious		Serious	
	Early Event*	Late Event**	Early Event*	Late Event**
Device Related				
None	0	0	0	0
Implant Procedure Related				
Hematoma	1	0	0	0
Catheterization Procedure Related				
Hypotension	1	0	0	0
Medication reaction/allergy	1	0	0	0
Respiratory acidosis	1	0	0	0
Respiratory insufficiency	1	0	0	0
Retroperitoneal hematoma	1	0	0	0
Stridor	1	0	0	0
Urinary retension	1	0	0	0
Vocal cord paresis	0	1	0	0
Catheter induced arrhythmia	0	0	1	0
Cyanosis (new cardiac disease)	1	0	0	0
Pleural effusion	0	1	0	0
Supraventricular tachycardia	1	0	0	0

* = Early event is ≤ 30 days from implant
** = Late event is > 30 days from implant

One fenestrated Fontan patient died 7 months post implant. The death occurred after many weeks of worsening symptoms of heart failure. An independent safety committee reviewed this case and determined that the death was attributed to the patient's underlying cardiac condition.

7.2 Potential Adverse Events:

Placement of the CardioSEAL involves using standard interventional cardiac catheterization techniques. Complications commonly associated with these procedures include, but are not limited to:
Air Embolus
Allergic dye reaction
Anesthesia reactions

Apnea
Arrhythmia
Death
Fever
Headache / Migraines
Hematoma and/or Pseudoaneurysm including blood loss requiring transfusion
Hypertension; Hypotension
Infection including Endocarditis
Perforation of Vessel or Myocardium
Stroke / Transient Ischemic Attack
Thromboemobolic events
Valvular regurgitation.

Fractures of the framework have been reported in some patients implanted with this CardioSEAL and a previous generation device when used in applications other than Fenestrated Fontan repair. In the independent, multicenter clinical trial sponsored by Children's Hospital, Boston, Massachusetts, the arm fracture rate was 0% in the Fenestrated Fontan population.

7.3 Observed Device Malfunctions:

There was one report of difficulty in releasing the device from the delivery system. The device was successfully released and delivered to the defect site.

8. CLINICALSTUDIES:

Study Design/Objective: The multi-center clinical trial conducted by Children's Hospital, Boston, Massachusetts, is a prospective, non-randomized trial studying the use of the CardioSEAL® Septal Occlusion system to close a variety of hemodynamically significant defects. The risks of surgical closure for the patients enrolled in this trial are sufficient to justify the known and potentially unknown risks of transcatheter closure with the CardioSEAL device. The study (referred to as the High-risk study) is ongoing and is summarized below. Data from patients undergoing fenestrated Fontan closure was extracted from this study.

Fenestrated Fontan Patient Entry: Patients were considered for enrollment in the High risk study if they had complex single ventricle physiology, and had previously undergone a Fontan procedure that included intentional placement of a fenestration within the Fontan baffle. An independent peer review group determined whether a patient should be enrolled into the trial based on the following criteria:

- the patient had a type of defect that was technically difficult or impossible to close surgically, such that the surgical risks were sufficient to justify the known and potential unknown risks of the device, or

- the patient's overall medical condition was such that the surgical risks were sufficient to justify the known and potential unknown risks of the device.

Methods: After enrollment, patients underwent cardiac catheterization. Position and size of the defect were confirmed by angiography. A hemodynamic assessment was performed pre-implant, and after test occlusion of the defect with a balloon. When these data suggested that the defect contributed to unfavorable hemodynamics and was feasible for transcatheter closure, device placement proceeded. Patients received aspirin, 1mg/kg/day, rounded to the nearest half tablet of 80 mg size, for at least six months following the procedure.

Patients were seen for follow up assessments as described in Table 2:

Timing of Evaluations – Table 2

	Pre-Implant	In Cath Lab	Pre-D/C	1 month F/U	6 month F/U	12 month F/U	24 month F/U
Cardiac HX/PE	X		X	X	X	X	X
Chest X-Ray	X		X	X	X	X	
Fluoroscopy					X		X
Echo/Doppler	X		X	X	X	X	X
O_2 Saturation	X		X	X	X	X	X
EKG (rhythm)	X		X	X	X	X	X
Severity of illness	X		X	X	X	X	X

Primary Endpoints: A 5-category ordinal scale (Severity of Illness scale) was used to measure clinical status. The scale took values from 1 to 5, and was constructed so that an improvement by one category (e.g., from category 1 to category 2, or from 2 to 3) would be considered clinically meaningful (refer to table 2). Any patient who died during the study would receive a value of 0 Data used in the construction of the scale were measured objectively by diagnostic laboratory tests, documented clinical status, or echocardiography. The data were collected prospectively before device implantation, at discharge from the hospital, and at each follow-up visit, so that patient classification at each time point could be implemented using a computer algorithm.

The major criteria by which severity was categorized for patients undergoing device placement for Fontan baffle fenestration closure, were the measurements of in oxygen saturation in room air and hematocrit. In addition to decreasing oxygen saturation and increasing hematocrit, a patient could be placed in category 1 if cyanosis was sufficiently severe to cause the patient to be ventilator dependent. The 5 categories and corresponding oxygen saturation and hematocrit values are provided in Table 3.

Severity of Illness Scale - Table 3				
1	2	3	4	5
≤ 70% 0_2 sat in room air or ventilator dependent or Hct ≥ 70	79-71% 0_2 sat in room air or Hct > 65-69	80-87% 0_2 sat in room air or Hct ≥60-64	88-94% 0_2 sat in room air	≥ 95% 0_2 sat in room air

Additionally an assessment of the echocardiographic closure status was made at each time point both at the evaluating facility, and by an unaffiliated core laboratory. Residual flow was assessed using Doppler color flow mapping, and graded using the following guidelines:

"Trivial" to "Absent": barely detectable or no detectable residual color flow through the defect. If flow present, it was a single color flow jet, well-circumscribed, with a proximal jet width measuring less than 1 mm in diameter in all views.

"Small": single color flow jet, well-circumscribed, and measuring 1-2mm (maximal proximal width) in all views in infants and children weighing less than 20 kg, or between 1 and 3 mm in diameter in larger children and adults.

"More than small": single color flow jet, well-circumscribed, measuring greater than 2 mm in diameter in all views in infants and children weighing less than 20 kg, or greater than 3 mm in diameter in all views in larger children and adults.

Results: At the time the fenestrated Fontan data was analyzed, 83 patients with no additional anatomic lesions were enrolled in the study for closure of fenestrated Fontan. Enrollment occurred at three investigational sites, with one site enrolling 92% of the patients. Sixteen of these patients did not have a device implant attempted due to defect smaller than anticipated (10), defect larger than anticipated (1), unfavorable anatomy (2), did not tolerate test occlusion (2), and the decision to surgically close the defect at the time of pacemaker implant/lead replacement (1).

Among the 67 patients treated with a CardioSEAL device, there were 39 (58.2%) males and 28 (41.8%) females. The age of the patients ranged from 2 years to 43 years, with a median age of 7 years.

Device placement was successful in all 67 patients in whom an implant was attempted. A single device was implanted in each patient. Because of the small size of baffle fenestrations, only 17mm and 23mm devices were used. All of the implanted devices remained stable throughout the follow-up period. None of the devices embolized or were explanted.

Table 4 reflects the number of patients observed within each oxygen saturation category at each visit. The available data column presents the number of patients with data available (numerator) and the number of patients who were expected to be seen at the respective visits (denominator).

Oxygen Saturation Results – Table 4						
	Category					
Time point	≤ 70 %	71 - 79 %	80 - 87%	88 - 94%	≥ 95%	Available Data
Initial	1	10	39	16	0	66/67
Discharge	0	0	3	45	17	65/67
1 Month	0	0	1	28	28	57/65
6 Month	0	0	0	28	21	49/52
12 Month	0	0	3	13	22	38/38
24 Month	0	0	1	8	4	13/13

Table 5 reflects the number of patients observed within each Severity of Illness category at each visit.

Severity of Illness Results – Table 5							
	Category						
Time point	0	1	2	3	4	5	Available Data
Initial	0	1	10	39	16	0	66/67
Discharge	0	0	0	2	45	16	63/67
1 Month	0	0	0	2	26	26	54/65
6 Month	1	1	0	0	28	22	52/52
12 Month	0	0	0	3	13	18	34/35
24 Month	0	0	0	0	6	4	10/10

Table 6 reflects the number of patients observed within each echo closure category at each visit.

Echo Closure Status Results – Table 6				
	Category			
	None - Trivial	Small	More than small	Available Data
Initial	7	48	7	62/67
Discharge	52	3	0	55/67
1 Month	33	0	0	33/65
6 Month	46	1	1	48/52
12 Month	23	0	0	23/35
24 Month	6	0	0	6/6

9. HOW SUPPLIED:

The implant and delivery system are packaged separately. The delivery system is size matched to the implant. Both components are provided sterile. Product is sterilized via ETO.

10. DIRECTIONS FOR USE:

A. Detailed Product Description:

The CardioSEAL Septal Occlusion System consists of two primary components. The CardioSEAL (Occluder) is comprised of a metal alloy (MP35n) framework to which polyester fabric material has been attached.

From the center of the CardioSEAL, a small wire with a pin at its end extrudes out at approximately 90 degrees to the plane of the CardioSEAL. The CardioSEAL is attached to sutures through a loading funnel. The loader should always be connected via sutures to the side of the CardioSEAL opposite the side from which the pin wire extrudes.

The delivery catheter is comprised of a coaxial catheter shaft through which a spring guide travels, connected to a solid control rod. At the proximal end of the control rod, a control handle is connected to an inner control wire, which courses through the spring guide to the distal end of the catheter shaft, where it terminates within a small tubular sleeve. The control wire terminates at the distal end in a pin, for attachment to its mate on the CardioSEAL. When retracted, the pin slides inside the sleeve. The distal end of the catheter terminates in a pod. Retraction on the control rod moves the sleeve into the pod. Refer to figure 1 for an illustration of the delivery system and CardioSEAL.

B. CardioSEAL Size Selection and Inspection:

Selection of an appropriately sized CardioSEAL(O) should be based upon measuring the defect diameter through the use of a sizing balloon (stretched defect diameter - SDD), procedural angiography and/or transesophogeal echocardiography, unless the size of the defect is known from the medical record. It is recommended that the CardioSEAL to Stretched Defect Diameter ratio (O:SDD) be 1.7-2.0:1 , and that the area containing the target defect be large enough to allow the CardioSEAL to fully deploy. The defect and surrounding structures should be fully examined in multiple planes to assure proper sizing of the CardioSEAL.

Prior to use, inspect the delivery system and CardioSEAL for signs of damage, such as kinks or bends in delivery wire or framework of the CardioSEAL. Check for secure attachment of the fabric to the framework.

Manipulate the delivery system and actuate the control handle to ensure that the attach release pin exits and retracts into the sleeve, and that the spring guide wire exits and retracts into the pod.

The delivery catheter system and CardioSEAL are packaged separately. Each is a component of the system, however, and each implant requires an equivalently sized or larger delivery catheter for appropriate use.

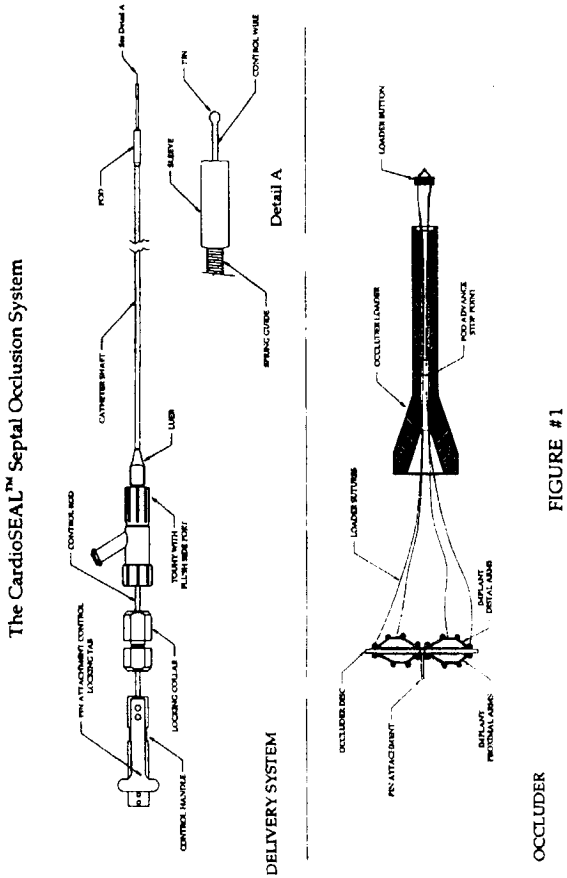


FIGURE #1

C. Preparation for Delivery:

Attaching the CardioSEAL to the Delivery Catheter:

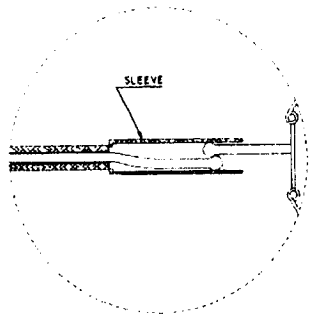
NOTE: Attachment and loading of the CardioSEAL *into the delivery catheter should not occur until*

a. the defect has been determined to be of appropriate size and position to accomodate the CardioSEAL, and

b. access to the defect with an appropriate French size and length introducer sheath has been obtained.

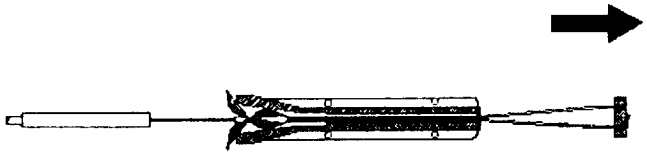
1. Loosen the black locking collar on the delivery catheter and advance the control rod until the sleeve exits from the pod. Pull gently upward on the pin control locking tab on the control handle. Push the rear section of the control handle in, extruding the pin from the sleeve about 3 – 4 mm.

2. Place the pin of the CardioSEAL into the sleeve, behind the pin extruding from the sleeve. Draw both pins into the sleeve by lifting up on the control handle tab and pulling the rear section of the control handle out. Seat control tab into slot on control handle, and test for secure attachment of CardioSEAL to delivery system with a gentle to and fro motion of the CardioSEAL.

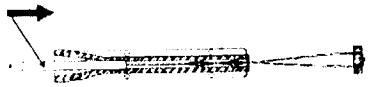


3. Submerge the loader/ CardioSEAL assembly in sterile saline and thoroughly soak the CardioSEAL. Make sure inner lumens of loader are wet. This will decrease friction between CardioSEAL and loader during loading.

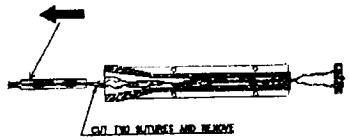
4. Carefully draw the CardioSEAL into the smallest section of the loader by pulling on the loader button. Do not attempt to force CardioSEAL into funnel section of the loader unless all four arms on each side of the CardioSEAL are appropriately retracted into the collapsed position.



5. With the CardioSEAL fully collapsed in the smallest section of the loader, use the control rod to advance the pod into the loader until the pod contacts the stop point.



6. Holding the pod firmly in the loader, retract CardioSEAL into the pod through the use of the control rod. Once in the pod, remove pod from loader, snip sutures one at a time, and remove from the CardioSEAL. Discard loader, sutures and loader button.



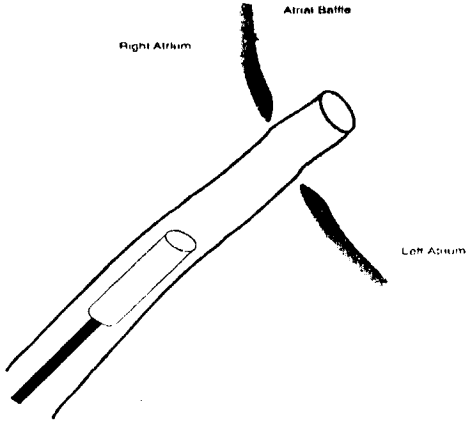
7. Loosen locking collar and advance it up to the Y-body. Tighten locking collar and flush the delivery system with normal saline several times to remove all air from the system. The CardioSEAL is now ready for delivery to the defect.

D. Insertion

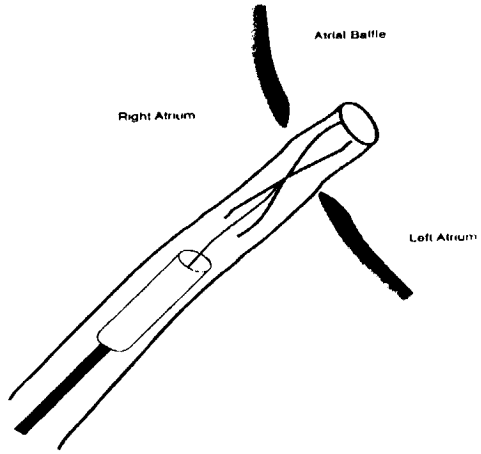
NOTE: As previously discussed in Section C, Preparation, Note B, an introducer sheath of sufficient French size (11F) for the CardioSEAL *and of adequate length to reach the target defect should have been placed via the venous system across the defect.*

1. Reposition sheath across the fenestration so that the distal tip of the sheath is approximately 1cm into the distal side of the fenestration. Thoroughly irrigate the previously placed introducer sheath to minimize risk of air entry and air embolus.

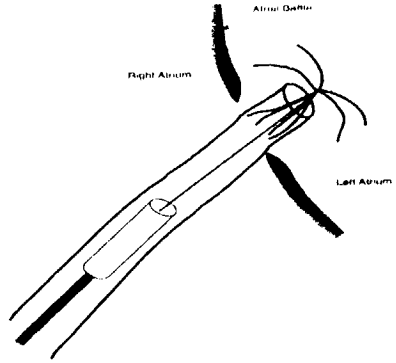
2. Insert the pod of the delivery system into the sheath, and advance until the pod is no closer than 5 to 10 cm from the tip of the sheath. The pod should be in the fluoroscopic field of view.



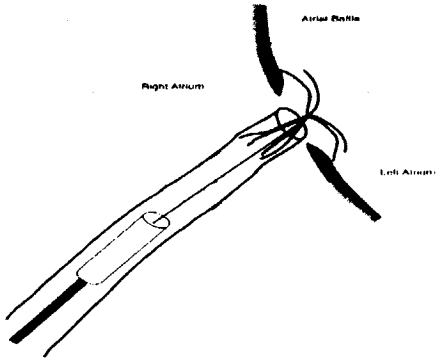
3. Loosen the locking collar nut and advance the collapsed CardioSEAL out of the pod and into the sheath. The CardioSEAL will remain collapsed within the sheath, with the sheath serving as an extension of the pod. Continue to advance the CardioSEAL until it is within 1-2mm of the tip of the sheath.



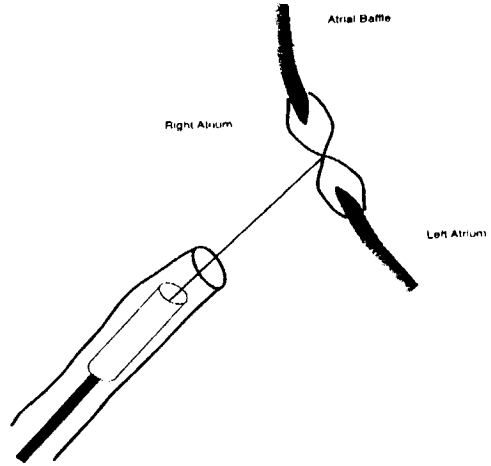
4. Recheck sheath tip position to verify location on distal side of fenestration. Holding the sheath and catheter steady, advance the distal set of CardioSEAL arms out of the sheath by moving the control rod forward. Alternatively, open distal set of CardioSEAL arms by retracting sheath off of the distal arms. Under fluoroscopy and transesophogeal echo, ascertain that all four distal CardioSEAL arms have fully deployed and are intact.



5. Holding the sheath and catheter steady, retract entire sheath – catheter - CardioSEAL system until the distal CardioSEAL arms approximate or engage the distal wall of the fenestration.

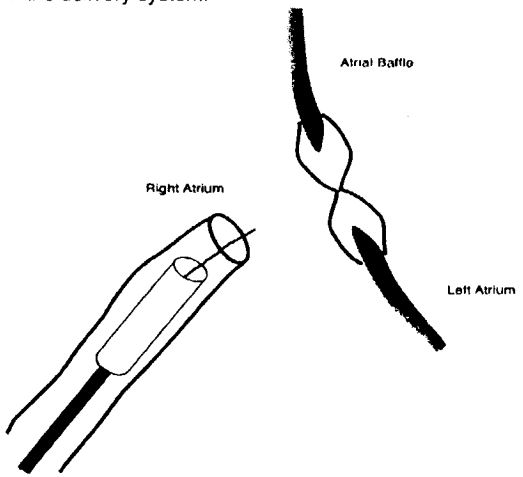


6. Once approximated or engaged, retract CardioSEAL Further to slightly flex the CardioSEAL arms. Retract sheath off of proximal CardioSEAL arms while maintaining position in the fenestration. This will release the proximal arms of the CardioSEAL to engage the proximal fenestration wall.



7. Allow delivery catheter and sheath to assume a neutral (i.e. no retraction) position and confirm correct placement of all arms on appropriate sides of the fenstration.

8. Once proper positioning is confirmed, advance the pin from the sleeve using the control handle at the proximal end of the delivery system. This will release the CardioSEAL from the delivery system.



9. Remove delivery system from sheath.

11. PATIENT INFORMATION:

The following counseling information should be provided to the patient:

Patients should be reminded of the importance of adhering to their aspirin and endocarditis prophylaxis regimens.

If an MRI is required, the patient should inform MRI staff of the presence of the CardioSEAL.

Patients should be encouraged to contact their physician if they have any questions or concerns

A patient brochure is available and is entitled; "A Patient's Guide to Transcatheter Defect Closure using the CaridioSEAL® Septal Occlusion System."

PL#:0250.00

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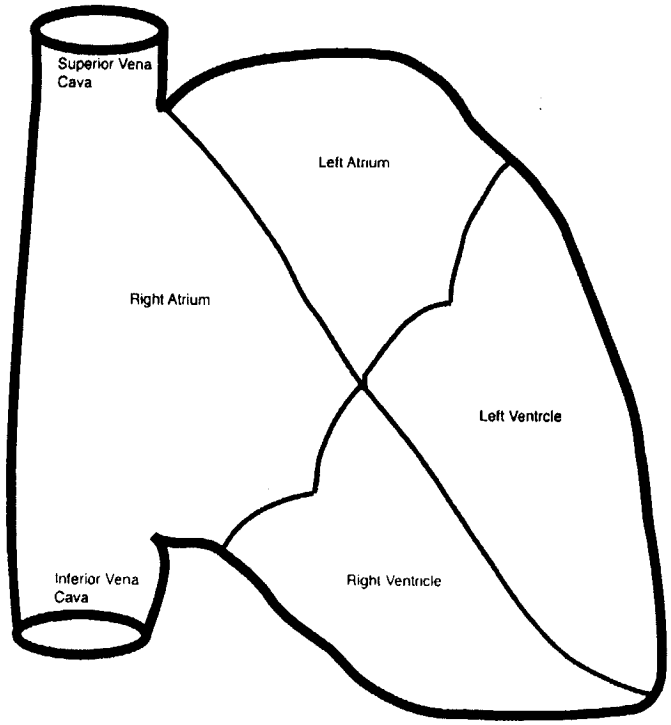
A Patient's Guide to Transcatheter Hole Closure of a Fenestrated Fontan using The CardioSEAL® Septal Occlusion System



Basic Diagram of the Normal Heart

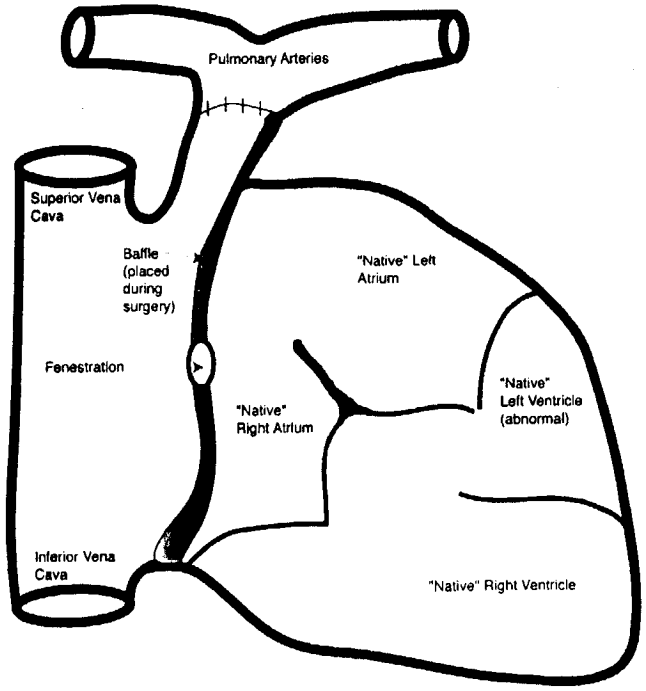
Humanitarian Use Device

Authorized by Federal law for use in the treatment of patients with complex single ventricle physiology who have undergone a fenestrated Fontan palliation procedure and require closure of the fenestration. The effectiveness of this device for use in this indication has not been demonstrated.

Introduction:

You (or your child) previously had a surgical procedure called a Fontan Palliation Procedure in which a "baffle" was constructed in the heart to assist with blood circulation. This

procedure also included the surgeon making a small hole ("fenestration") in the baffle to help relieve the symptoms of the original heart disease. (see diagram below)

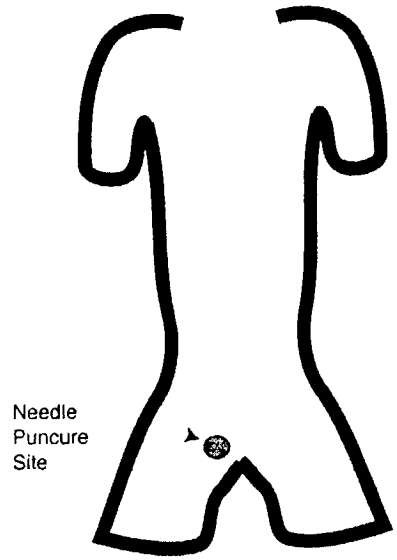


Example of "Fontan" anatomy after surgery illustrating placement of the atrial baffle.

Your (or your child's) physician has recommended that this small hole should now be closed using an implant. The implant is placed in the heart using a catheter. This procedure is called Transcatheter Hole Closure. It is an alternative to open heart surgery. The physician believes that the risks of open heart surgery presents an unusually high risk to you (your child). Transcatheter closure is a procedure that avoids the need for open heart surgery. As a less invasive procedure, it is believed to present fewer risks since open heart surgery is avoided.

How does Transcatheter closure work?

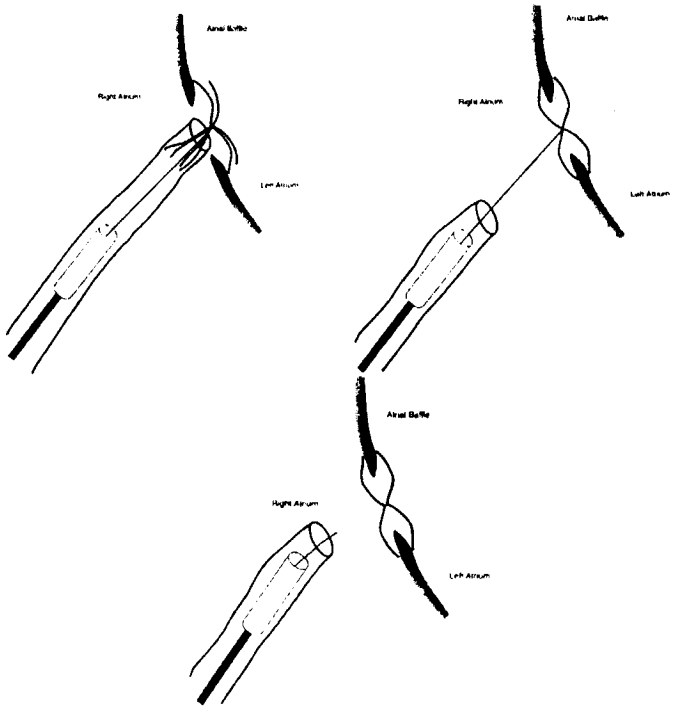
Transcatheter closure is performed in the Cardiac Catheterization Laboratory by a Doctor. The Doctor will gain access to your (your child's) heart by getting access to a major vein in the groin.



This is done by a needle puncture. Various catheters will be advanced from the groin or arm into the heart. Moving pictures, called angiograms, will be taken to better visualize the heart and the hole. The Doctor may use a special ultrasound device, called TransEsophogeal Echocardiography (TEE). This is another way to better see the heart and the hole. The TEE involves putting a probe into the esophagus, the tube between the mouth and stomach. These tests are used to determine which sized implant the physician will use to close the hole.

The appropriate size implant is attached and collapsed for placement into a special catheter. The catheter is then advanced to the site of the hole. The Doctor re-expands the implant so that part of it sits on each side of the hole. In

effect the hole is gently sandwiched between the two sides of the implant. The implant is then released from the catheter. The catheter is removed and the procedure completed.



Diagrams showing the basic steps of the procedure.

Will I be awake during the procedure?
This is up to the physician. Many patients are put under general anesthesia for this procedure. A local anesthetic is used to numb the groin or arm (the location where the catheters are inserted).

How does the implant stay in place?
CardioSEAL is made from two, small diameter wire frameworks. The framework has a special fabric attached to it. The device looks like two little umbrellas set edge to edge. Each umbrella framework has special springs. This allows the umbrellas to spring towards the hole. This very slight tension, along with the blood in the heart, holds the device in place. Over time, tissue grows into the fabric and the implant becomes part of the heart.

What does the Implant look like?
CardioSEAL comes in several sizes. The smallest (17mm measured diagonally) is about the size of a dime, the largest is about size of a half- dollar. This picture shows one of the larger implants placed next to a dime. This may give you some perspective of the size. The framework is made from a metal frequently implanted in the body during other surgeries. The fabric is the same fabric the surgeon would use if open heart surgery was performed.

What are the risks?
The risks are similar to those associated with other heart catheterization procedure. There are additional risks associated with the implant. Examples include:

- dislodgement
- incomplete sealing of the hole
- abnormal heart rhythms
- bruising at the groin or arm
- changes in blood pressure
- air embolus
- apnea
- headache/migraine
- infection including endocarditis
- perforation of vessel or myocardium

- thromboembolus
- stroke or TIA

The implanting physician usually insures that the risks associated with heart catheterization and the implant are reviewed with each patient.

Will the procedure hurt?
Usually not. After the procedure, some patients report tenderness at the groin or arm. Some also complain of a sore throat from the TEE probe. Patients cannot "feel" the implant.

What is the special care after the procedure?
- bed rest for a period of time (this allows the implant to firmly stabilize)
- restriction from heavy lifting or other physical activities for a period of time
- take a blood thinning product, such as Aspirin, every day, for a period of time (perhaps several months or longer)
- take antibiotics to prevent infection (this may be required when going to the dentist or having a minor surgical procedure)
- follow the doctor's instructions precisely
- call the doctor if there are any questions

What about follow up visits?
All patients are asked to see their doctor for follow up visits. The Doctor will provide specific instructions for follow-up care.

Does the Implant stay in for the rest of my life?
Yes, it is intended to stay in forever.

Can I go through metal detectors, or have an M.R.I?
Yes. The implant will not set off metal detectors. The metal framework is not magnetic. It will not be affected by an MRI, but the picture taken by the MRI might have a fuzzy quality. If an MRI is needed, the MRI staff should be informed about the presence of the implant.

What are the options or alternatives to this treatment?
Having open heart surgery to close the fenestration is an option. Or, you may elect to have no treatment of any kind.

What are the contraindications to this treatment?
- presence of blood clots in the vein used to introduce the catheter
- the vein needed to introduce the catheter is too small for the catheter to fit
- presence of an active infection
- patient unable to take aspirin or other blood thinning medication

Glossary of technical terms
- **Abnormal heart rhythms** – abnormal heart beats.
- **Air embolus** – an air bubble in the blood stream.
- **Angiogram** – a test involving moving pictures of the heart.
- **Apnea** – a transient cessation of breathing.
- **Atrium** – the upper two chambers (right and left) of the normal heart.
- **Fontan palliation procedure** – a surgical procedure that helps relieve the symptoms caused by only having one of the two heart ventricles working properly.
- **Baffle** – a section of medical grade material which is surgically implanted as a tube or patch to redirect blood flow in the heart.
- **Cardiac Catheterization Laboratory** – a room in the hospital dedicated to accessing the heart using catheters and X-ray guidance.

- **Catheter** – a sterile tube for insertion into a vessel to permit injection or withdrawal of fluids or to pass material through.
- **Dislodgement** – moving from its intended position.
- **Endocarditis** – an inflammation of the lining of the heart and its valves.
- **Esophagus** – the part of the body which connects the mouth to the stomach.
- **Fenestrated Fontan** – a term used to describe a small hole purposely made by the surgeon as part of the Fontan palliation procedure.
- **Heart catheterization** – a less invasive way (compared to open heart surgery) to access the heart using the arteries of veins.
- **Implant** – a medical device which is put into the body.
- **MRI** – Magnetic Resonance Imaging--a type of test used to visualize body tissue that uses a magnetic field.
- **Native** – refers to a condition that was (or is) naturally present to the body at birth.
- **Perforation of vessel or myocardium** – a tear in a blood vessel or the heart.
- **Pulmonary Arteries** – major blood vessels that direct blood from the heart to the lungs.
- **TEE** – an ulstrasound (sound waves) test to visualize the heart and hole.
- **Thromboembolus** – a blood clot within a blood vessel.
- **TIA** – (transient ischemic attack) a transient lack of oxygen to the brain.
- **Transcatheter Hole Closure**- a less invasive procedure (compared to open heart surgery) used to close heart holes using catheters.
- **Ventricle** – the lower two chambers (right and left) of the normal heart.

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This guide was prepared by Nitinol Medical Technologies, Inc. It is based on input and guidance from Physicians and Clinical Staff throughout the United States. NMT wishes to thank them for their contributions. However, this guide is not a replacement for speaking with your physician. We recommend you write down questions for your doctor on a separate piece of paper.

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